

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES		
2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than Item 6)	CODE

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State, and ZIP Code)	(x)	9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM II)
		10A. MODIFICATION OF CONTRACT/ORDER NO.
		10B. DATED (See Item 13)
CODE	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

- (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

**13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS.
IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.**

(x)	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☐ is not, ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Except as provided herein, all terms and conditions of the document referenced in item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)		
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(Signature of person authorized to sign)		(Signature of Contracting Officer)	

The purpose of this amendment is to:

- 1) Respond to questions received from potential offerors;
- 2) Incorporate amendments to the Statement of Work and the Delivery Schedule; and
- 3) Extend the due date for receipt of proposals.

As a result of the questions we have received, it has been determined that the server for this project should reside at AHRQ facilities at 2101 East Jefferson Street, Rockville, MD. Therefore, some changes were made to the Statement of Work and Delivery Schedule. Those revised sections are attached at the end of this amendment. **Also, please note that the Contractor shall be required to use the Microsoft Windows 2000 operating system for this project.**

Due to the volume of questions received and the time required to respond to those questions, the proposal receipt date is hereby extended until **Tuesday, April 17, 2001, at 1:00 p.m., local time.**

PLEASE NOTE: THE ADDRESS FOR RECEIPT OF PROPOSALS IS CHANGED DUE TO THE RELOCATION OF THE DIVISION OF CONTRACTS MANAGEMENT OFFICES. PROPOSALS SHOULD BE MAILED TO:

**AGENCY FOR HEALTHCARE RESEARCH AND QUALITY
DIVISION OF CONTRACTS MANAGEMENT
2101 EAST JEFFERSON STREET, SUITE 502
ROCKVILLE, MARYLAND 20852**

FOR HANDCARRIED PROPOSALS, PLEASE DELIVER TO:

**AGENCY FOR HEALTHCARE RESEARCH AND QUALITY
DIVISION OF CONTRACTS MANAGEMENT
2101 EAST JEFFERSON STREET, SUITE 502
5TH FLOOR, EAST WING, ROOM 5E117
ROCKVILLE, MARYLAND 20852**

Below are the answers to the questions received concerning this solicitation:

1. **Question:** The RFP specifies that the intended audience of the Web site (i.e., the users of the system) is physicians. The RFP states, "The project's end products are intended to be used by physician trainees as well as practicing physicians." (p. 8). The RFP does not specify, however, who may submit case abstracts to the system. Should the Contractor accept case abstracts only if they are submitted by a physician, or may anyone (e.g., nurses, patients, orderlies) with substantive knowledge of a near miss event submit a report? May individuals from outside the US submit near miss event reports?

Answer: Page 8 of the RFP notes that "This project is an initial, focused effort that builds upon traditional, physician-operated morbidity and mortality conferences. The project's end products are intended to be used by physician trainees as well as practicing physicians. Based on the success of this project, the Agency may consider broadening its efforts include similar activities for other disciplines (e.g., nursing). The intent of the project is to advance learning with a primary focus on U.S. healthcare.

2. **Question:** Page 8, SOW Statement, Paragraph 1.1 - Do "near misses" include morbidity?

Answer: As stated in the RFP, page 8, footnote 1, "Near misses are defined as errors that do not result in harm or injury."

3. **Question:** Is the scope of the system limited during the design phase to one large hospital or no more than five hospitals in one medical system or region within one State?

Answer: No such specifications exist in the RFP.

4. **Question:** Reference Page 9. Security and confidentiality - What level of security is required? For instance, would the government accept an approach similar to the common criteria currently utilized by the National Security Agency (NSA) and the National Institute for Standards and Technology (reference "Controlled Access Protection Profile, V1d, Information Systems Security Organization, NSA, October 8, 1999)?

Answer: Offerors should propose the appropriate level of security and technical approach to assure information systems security and confidentiality based on the sensitivity and use of the data, and in accordance with the following laws and regulations:

- 42 U.S.C. Subsection 299c-3(c)
- Computer Security Act of 1987 (P.L. 100-235)
- Privacy Act of 1974 (P.L. 93-579)
- Clinger-Cohen Act (Information Technology Management Reform Act of 1996 - Division E of P.L. 104-106)

- Office of Management and Budget (OMB) Circular No. A-130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources
- Presidential Decision Directive 63 (PDD-63), Critical Infrastructure Protection, May 22, 1998
- HHS' Automated Information Systems Security Program Handbook

5. **Question:** Section C, Specific Requirements, subsection 1.1 (b) on page 9, the RFP states that it is required to “develop an automated system that uses off-the-shelf software to analyze pooled data and text from abstracts, full case summaries, and Web-based electronic dialogue about posted summaries, all of which shall be used as input for an annual report”. What type of analysis is needed? Can you provide an example.

Answer: Examples of analysis are not being provided although an Offeror could search recent, relevant literature to identify some examples showing categories of medical error that would be of interest [e.g., system failures such as technical (equipment, physical installations, software, materials, labels, forms) and organizational issues (protocols, procedures, transfer of knowledge, management priorities, culture), and human behavior (inability of an individual to apply his/her knowledge, qualifications, coordination, verification, intervention, monitoring)]. Using input as depicted in the RFP, the offer should describe the categories of information collected that would be most beneficial to those who are expected to use and gain educationally from the information as noted on page 8 in the RFP. Keep in mind that the purpose of the project is to advance learning from near misses and improve patient safety by reducing the risk for near misses.

6. **Question:** (a) Can you say more about what kind of knowledge do you hope to gain from the “text data analysis”? (b) Is there a particular genre of off-the-shelf software that you have in mind?

Answer: See answer to part a of the previous question. One off-the-shelf software that could be used is NUD*IST; however, there may be other suitable software programs.

7. **Question:** Is there a preference for how and where the website is hosted?

Answer: The website will be hosted at AHRQ. All servers and related hardware and software to operate, maintain, backup and restore the site will reside at AHRQ. AHRQ will provide the necessary Internet service connectivity and firewall security hosting service. The cost of this Internet service connectivity and firewall/physical premises facility security hosting service should not be included in the Offeror's proposed budget. However, the Offeror must specify and propose all other hardware, software, and components to fully operate, maintain, backup/recover, support, secure and manage the system and its 24x7 operations. All hardware support will also be carried out by AHRQ and these costs shall not be included in the Offeror's proposed budget.

8. Question: Reference Page 10, Disaster recovery - What are the availability and reliability requirements (MTBF)?

Answer: The site must be operational 24x7. AHRQ has an offsite disaster / recovery second computer room location. This offsite secondary location will be used for disaster recovery of the primary system. This secondary offsite location is connected to AHRQ's primary computer site via Government-owned fiber cabling. The connection operates at gigabyte speed using an IP Ethernet based transmission protocol. The Offeror shall specify and propose a detailed disaster recovery architecture and configuration solution for all primary and secondary website, database, load balancing, maintenance, troubleshooting, backup/recovery and other needed hardware, software and equipment part numbers and configurations to ensure 24x7 operations, hot-site backup recovery and fail-over redundancy in the event of a disaster. The Offeror shall specify part numbers and configurations from the latest COMPAQ Proliant server line for appropriate servers to operate and backup this system. This specification is required to maintain server consistency and ensure cost-effective server support across AHRQ's existing multiple computer systems. The Offeror may specify and propose other make and model solutions as appropriate for all other hardware, software, and needed components of a total operations, maintenance, and disaster backup/recovery solution. Also the Offeror shall specify and propose the latest enterprise version of Oracle software for all database management and administration functions and data and process modeling and design components of the system.

9. Question: Reference Page 10, Documentation - What format/media?

Answer: Documentation should be prepared using Microsoft Word, Excel, PowerPoint and Visio software as appropriate, and submitted to AHRQ both in hard copy and on diskette.

10. Question: Page 10, Database management and model requirements - What are the capacity requirements for the DBMS?

Answer: The Offeror should specify and propose the latest enterprise version of Oracle software and licensing for the DBMS and follow Oracle's guidelines and procedures for determining sizing and configuration settings and estimates. The Offeror shall use the Oracle Advanced Security Options and any needed encryption technology, and other technologies and solutions, as appropriate, to secure system data and files and shall include and document any such design considerations in any DBMS sizing and capacity estimates.

11. Question: What are the storage requirements?

Answer: The Offeror should determine database and other system storage sizes, hard drive architecture configurations, etc. based on an analysis and estimate of data and system requirements.

12. Question: What is the expected number of records?

Answer: The contractor should estimate the number of data base records based on the volume of abstracts anticipated to be submitted. See answer to Question 13 on volume of participation and submissions.

13. **Question:** What is the expected number of users, average and range, on a per day/per month basis? What is the expected number of hits per day?

Answer: There are no historical data upon which to develop accurate estimates. However, for the purposes of planning and estimating costs, in the first year of operation, the anticipated number of user sessions on the web site is estimated at 200 to 600 per day. In the following year, it is estimated that the web site will be accessed twice as frequently as the previous year. The number of web site connections may exceed the numbers stated, and the Offeror shall have the ability to support those users in excess of what the Agency has estimated. The Contractor shall plan for a load tolerance of at least 200 to 400 simultaneous users.

14. **Question:** What volume of near miss abstracts (and over what period) does AHRQ anticipate being submitted to the contractor? AHRQ may reasonably respond to this question that bidders should use their own best judgment in making volume assumptions in their proposals. However, this will result in each bidder submitting a proposal predicated on a different volume assumption. If one accepts the premise that each bidder's educated guess is just that—a guess—and is as reliable as all others despite their differences, proposals will not be comparable on a cost basis. Therefore, we believe it is prudent for AHRQ to specify an assumed volume of submissions to enable a truly valid comparison on cost-based evaluation criteria?

Answer: There are no historical data upon which to make estimates. The volume of participation i.e., submission of abstracts will be driven by the Contractor's success in raising awareness of the project and promoting participation in it. **For costing purposes only, the Government estimates that at a minimum 30 abstracts will be received and reviewed for each case summary posted on the web site.** The offeror shall be prepared to handle workloads in excess of this estimate.

15. **Question:** Reference Page 10, Hardware and software procurement - Should we bid the cost of hardware/software for the development environment?

Answer: Yes.

16. **Question:** Should we bid the hardware/software for the operations and maintenance of the proposed solution?

Answer: Yes.

17. **Question:** Reference Page 10, Information collection - What comprises "only those data necessary for the performance of the project?"

Answer: The contractor should determine the exact scope of data necessary to the performance of the project. Information collection must be in accordance with Federal data privacy laws. The contractor should not inappropriately collect nor use email, IP addresses, user statistics, activity logs, cookie technology logs, or other similar type of information. The Contractor shall not use "persistent" web cookies without approval of the Project Officer.

18. **Question:** Has the government defined the necessary data? If not, may the contractor propose the definition of the necessary data be part of requirements development?

Answer: The Offeror shall propose the definition of the necessary data as part of its requirements development process. However, the definition must comply with Federal data privacy laws.

19. **Question:** Section C, Specific Requirements, subsection 1.1 on page 10, the RFP states that the contractor shall provide a Disaster Recovery plan. What service level requirements are needed? In other words, how much redundancy should we have? How much down time is acceptable until the system is recovered? Obviously the less down time is required, the more expensive the system (hardware and software) will be.

Answer: The site must be operational 24x7. The Contractor shall provide the necessary website hardware and software architecture and configuration to provide redundancy fail-over in the event of a disaster. See answer to Question 8 for more detailed information on disaster recovery.

20. **Question:** Section C, Specific Requirements, subsection 1.1 on page 10, the RFP states that "The Contractor shall ensure that the web site is Bobby Approved". What does this exactly mean? Is there any reference to this standard?

Answer: Bobby is a free service/tool provided by the Center for Applied Technology (CAST) to help web page authors to help identify changes to their pages needed so users with disabilities can more easily use their Web pages. For example, a blind user will be aided by adding a sound track to a movie and a hard-of-hearing user will be aided by a written transcript of a sound file on a web page. Bobby will recommend that these be added if they do not exist. Many people with disabilities will use special Web browsers, such as one which reads text out loud using a speech synthesizer for blind users. The suggestions made by Bobby will help authors to add information to a Web page which will help the special browsers work more effectively. For more information, refer to the following URL: <http://www.cast.org/bobby>.

21. **Question:** Is the editorial panel, including the five Chief Residents, a voluntary panel? And if it is *not*, is the panel's operational cost part of the proposal budget, or it will be paid through AHRQ?

Answer: The Offeror should propose a voluntary or paid panel, justify its choice, and submit a budget reflective of the costs of its chosen option. Costs for honoraria, consulting fees, etc., shall be allowed as reimbursable costs if the Offeror selects a "paid" option for the Editorial Panel.

22. **Question:** Page 11, paragraph 1.2 (incentive and reward system) - Should the contractor bid only the design and implementation costs of fielding the incentive and rewards system since the government will approve the design of the incentive and rewards system?

Answer: The Offeror should identify and bid all costs in designing, implementing, and

maintaining the incentive and rewards system.

23. Question: Will the contractor be non-compliant if any monetary costs of the incentive and rewards system are not included in the proposal?

Answer: If the Offeror includes monetary costs of the incentive and rewards system in its plan, the costs shall also be included in the Offeror's budget .

24. Question: Will the contract be adjusted to pay for the rewards to the individuals after design approval?

Answer: The Offeror shall include estimated costs of the design in its proposal budget.

25. Question: Can the "incentives and rewards" include cash payments, course credit, and or contract-funded donations to charity?

Answer: Each or any combination of the proposed types of incentives and rewards would be acceptable.

26. Question: Reference Page 11, paragraph 1.3 (editorial panel) - Must all editorial panel members be physicians or may they be from other disciplines as long as they meet the criteria cited in paragraph 1.3?

Answer: Because the targeted audience for this project is physicians and physician trainees, the majority of the panel members should be physicians and physician trainees. However, it is critical to also include expertise in the domains noted on page 11, task 1.3 of the RFP. A single individual may represent expertise in more than one domain.

27. Question: Reference Page 11, paragraph 2 (user test and modify the national, web-based, blame-free learning program) - Is the contractor expected to support unlimited user-test driven modifications within the scope/funding of this solicitation?

Answer: The Offeror shall, as noted in the RFP, "test the program with a small sample of individuals....and the program shall be modified as necessary and appropriate." This task represents user/usability testing prior to full implementation. Page 12, Task 4 of the RFP states that the "Contractor shall develop and implement a method to evaluate the usefulness and effectiveness of the program....Periodically the program shall be modified as necessary...." Task 4 is periodic and post-implementation whereas Task 2 is a one-time only pre-implementation.

28. Question: What are the exit criteria for satisfactory completion of the tasking described in this solicitation?

Answer: The system shall be deemed acceptable when it performs to the requirements outlined in the Offeror's best and final proposal, the contract with the agency, and the Offeror's final work plan as accepted by AHRQ.

29. **Question:** AHRQ has made provisions in the contract for the Contractor to be responsible for encouraging case abstract submissions via the incentive and reward system (Requirement 1.2, p. 11). However, AHRQ does not seem to have included any tasks related to specifically encouraging visits to or use of the information to be presented at the Web site. Such activities might include issuing press releases, Internet and trade publication advertising, developing media kits, developing tutorials, and other similar activities. Is this an omission in the RFP, or will AHRQ retain complete responsibility for promoting the Web site? What assistance, if any, is expected from the Contractor in these tasks?

Answer: The Offeror is responsible for establishing methods for raising awareness of and promoting participation in this project. However, AHRQ will use its traditional methods of notifying the public and specific interested parties about this project (e.g., a press release after the contract is awarded, mention at meetings in which AHRQ staff give presentations, mention in AHRQ's Research Activities, AHRQ booths at various meetings, a notation on and link through the AHRQ web site, etc.).

30. **Question:** Section C, page 11, subsection 1.2 is to design and implement an incentive and reward system. Is advertisement permitted on the web site that will be developed to fund this incentive and reward system? If not, is the incentive and reward system going to be part of the project development budget, or it will be an operational cost that AHRQ will allocate money for?

Answer: No advertisement shall be permitted on this web site. The incentive and reward system the offeror designs shall be part of its project budget.

31. **Question:** Is there a list of web browsers that the web application should support? Or is it enough to support the most popular browsers (Internet Explorer and Netscape)?

Answer: A text version of the site must be available for access by users with any browser. The website design must be Bobby approved and compliant with ADA Section 508 requirements.

32. **Question:** When does the government expect a fully operational nation-wide system; by the 12th, 24th or 36th month EDOC?

Answer: As noted in the RFP, page 15, item 7, the system is to be implemented 12 months from EDOC.

33. **Question:** May the contractor propose an incremental build and deployment approach to meet the intentions of the solicitation?

Answer: The intent of the question is unclear. However, the Government expects a system to be built and operational based on the schedule of deliverables noted on pages 14 through 16 of the RFP.

34. Question: Section C, subsection 1.4 on page 11 of the RFP, it is required to develop a confidential, legally protected system. Are there specific requirements that the AHRQ lawyers can provide to define a confidential, legally protected system, or do we have to consult a law firm of our own? If we have to consult with a law firm, should the consulting fee be added to the budget?

Answer: Note the requirements listed in the answer to Question 4. Also note that the case summaries to be put on the web shall be written in a way that no individual institution, provider, or patient is identifiable. Furthermore, the Offeror's system shall be designed so that, to the extent possible, reports submitting abstracts and case summaries are on notice that they are to report information in a manner that prevents individuals and organizations involved in a near miss incident from being identifiable. One unavoidable exception may be a reporter who is self-reporting, and there is a short term need to communicate with the reporter to clarify details of the abstract/case report. In such a case, the e-mail address, phone number, etc., provided for follow-up can be a means of identifying the reporter who self-reports a near miss and possibly of identifying the patient, the institution and other staff involved.

The report of near miss information (and others indirectly made identifiable as described above) should be identifiable only as long as is necessary to make certain that the particular information provided is clear and sufficient for the purposes of the project. Thus the need for follow-up information should be determined immediately and be acted upon in as short a time as possible. This ensures that identifiable information is potentially subject to access demands for a very short time and minimizes the risk of having to spend time on legal challenges. For the same reasons, the Contractor shall never keep any identifying information that is not needed. For example, upon receipt of an abstract/case summary, the Contractor's procedure shall provide for immediate screening for unnecessary identifying information and eliminate it, e.g., any real patient name, institution name, dated event, or a reference to a location that may have been inadvertently provided.

Most importantly, should there be any request from medical disciplinary bodies, subpoena, or compulsory order for identifiable data while the Contractor has such data, AHRQ's federal authorizing legislation, at 42 U.S.C. Subsection 299c-3(c) precludes any disclosure of identifiable information obtained by AHRQ's contractor for the purpose of carrying out this contract (unless the subject or reporting individuals have given consent to a disclosure but no such consent shall be solicited by the Contractor). This federal confidentiality statute would preempt any state disclosure requirements. AHRQ's legal counsel is available to provide guidance upon request, should a court order be issued for the disclosure of protected research information.

35. Question: Page 11, Item # 1.4 – Develop a confidential, legally protected system. Given that the morbidity and mortality peer review typically falls under the Quality Assurance (QA) programs in hospitals, what protection/immunity is being provided to prohibit the use of any reports in any disciplinary action or law suit?

Answer: See the answer to Question 34.

36. Question: The RFP states (p. 12) that the Contractor must “develop a method to ensure complete confidentiality and legal protection for all abstracts, case summaries, and their reporters, facilities, patients, etc.” Does AHRQ anticipate that the Contractor will be responsible for ensuring the privacy and confidentiality of individuals participating in the discussion lists required at the Web site

Answer: No. By the very nature of such discussions (e.g., through a chat room, listserv, etc.), identification of participants will be neither private nor confidential. Furthermore, the Contractor shall make such participants aware that what they write will be neither private nor confidential.

37. Question: Paragraph C.1.4 states "Develop a confidential, legally protected system. The Contractor shall develop a method to ensure complete confidentiality and legal protection for all abstracts, case summaries, and their reporters, facilities, patients," Please elaborate on the legal protections that AHRQ has in mind -- "ensure complete confidentiality and legal protection" are very strong words.

Answer: See answer to Question 34.

38. Question: Reference Page 11, paragraph 1.4 (legally protected system) - What are the evaluation criteria the government will use to determine whether the system is confidential and legally protectable?

Answer: The system shall comply to all of the requirements as noted in the RFP, the offeror's proposal, the contract with the Agency, the final work plan as accepted by AHRQ, and the bulleted items listed in the answer to Question 4.

39. Question: If the system is performing IAW the acceptance criteria defined by the government, will the government indemnify the contractor against any medical and other liability?

Answer: No.

40. Question: Will AHRQ defend any FOIA or subpoena requests delivered to the Contractor, its subcontractors, or their employees?

Answer: See the answer to Question 34.

41. Question: Reference Page 12, paragraph 4 (Assess the utility and effectiveness of) - What are the acceptance criteria the government will use to assess the utility and effectiveness of the learning program?

Answer: The Contractor shall be required to develop an evaluation plan to address the above question. That plan should include, but not be limited to, the extent to which the Contractor achieves participation of the target audience(s), provides useful information for improving graduate medical education, etc.

42. Question: Page 12, Item #4 – Assess the utility and effectiveness of the national, web-based, blame-free education and learning program. What are AHRQ's expectations of the project in terms of the types of educational experiences they will provide to institution, individuals submitting case studies, and the broader physician community?

Answer: Page 8 of the RFP notes that "This project is an initial, focused effort that builds upon traditional, physician-operated morbidity and mortality conferences...." Those M & Ms are institution-specific. This project shall be operationalized so that the lessons are not limited to the institutional boundaries but expanded well beyond those borders to all interested parties.

43. Question: Page 12, Item #4 – Assess the utility and effectiveness of the national, web-based, blame-free education and learning program. What are the AHRQ's expectations of the project in terms of the scope and level of evaluation of the impact of the learning interventions?

Answer: See the answer to Question 41.

44. Question: Is the contractor expected to support unlimited modifications within the scope/funding of this solicitation?

Answer: Task 4 notes "Periodically the program shall be modified as necessary...." The Offeror shall design and describe the periodicity of its plan; however, annual or semi-annual modifications could be considered acceptable schedules.

45. Question: In Section C, Specific Requirements, subsection 3 (e) on page 12, the RFP states that "the contractor shall analyze data from all formats (abstracts, summaries, and electronic dialogue) to report on "near misses" and methods to prevent or reduce their occurrence. Again, what type of analysis? Can you provide an example?

Answer: See the answer to Question 5.

46. Question: Section C, Specific Requirements, subsection 4 on page 12, it is required to evaluate the effectiveness of the system. Are there criteria to evaluate the effectiveness of the system? Is there a quantitative measure that we can use, or should we propose evaluation criteria in the proposal?

Answer: The Offeror shall be responsible for developing and describing its proposed plan to evaluate and test the effectiveness of this program.

47. Question: When will the funding decision be made and announced (rough estimate)?

Answer: Approximately June 15, 2001

48. Question: Reference Page 14, Section F- Period of Performance and Delivery Schedule, F.3 Delivery Schedule - What are the acceptance criteria for each of the deliverables?

Answer: In general, each deliverable shall be accepted when it meets the thresholds, specifications, etc., delineated in the Offeror's proposal, the contract with the Agency, and the

Contractor's final work plan as accepted by AHRQ.

49. Question: May the contractor propose an alternative delivery schedule within the stipulated Period of Performance?

Answer: No.

50. Question: The RFP states on page 61 that "the Project Director should have, at a minimum, a medical degree and be a practicing, licensed physician with expertise in medical education." Would a proposal be considered non-responsive if the bidder: a) designated a Project Director and/or Project Manager whose education and background were in a non-clinical discipline that was also necessary for this project's success (e.g., management expertise in leading multidisciplinary projects, tight schedule and fiscal control, IT development, etc.), and b) accessed clinical content and medical education expertise through another individual (to be designated as key personnel) represented in the project's core management team?

Answer: The requirements and evaluation criteria for this project remain as stated in the RFP.

51. Question: Reference Section L – Instructions, Conditions, and Notices to Offerors, L9 Technical Proposal Instructions, Key Personnel, Page 65, D1 - May a licensed physician who has vast experience in clinical medicine and extensive executive medicine experience with the requisite management credentials, qualify as the Program Director?

Answer: The instructions and evaluation criteria for this project remain as stated in the RFP.

52. Question: The RFP Section L, Proposal Instructions, affords bidders the opportunity to provide detailed information on relevant organizational qualifications and experience related to specific contracts. This information is included in the Past Performance Volume related to the contractor performance questionnaires that bidders will have completed by former and current clients. However, the proposal outline presented in the RFP Section L does not seem to provide an appropriate location for bidders to describe organizational experience in activities where there is no single client or where the relevant activities were not performed under a contract. Relevant products or services developed, sold, and distributed to hundreds or thousands of users/customers would fall into this category. Examples might include subscription publications, membership programs, large conferences, public or private Web sites, databases, and other similar activities. Where would AHRQ expect to find information on these kinds of activities in bidders' proposals? We like to include an additional section in the Past Performance Volume that contains this information. Is this acceptable, or would AHRQ prefer this information included in another location?

Answer: Refer to page 64 of the RFP (i.e., Section C Management Plan, item 1 states "Demonstrate corporate/organizational experience in managing projects of a similar size and nature) and page 66 of the RFP (i.e., Section D Key Personnel, item 2 states "Offeror shall provide evidence of availability, qualifications, and demonstrated experience of"

53. Question: Is it expected this product will be pilot tested? Although it is clear that the AHRQ is interested in developing a model that can be applied nationally, the scope of the project is so broad that it seems appropriate to develop the model along the lines of pilots that would be initially deployed within organizations or regions. Is this approach acceptable and if so, what is the expected depth and breadth of the pilot studies?

Answer: Refer to page 11, Task 2, of the RFP.

54. Question: Reference section B.4 - Provisions Applicable to Direct Costs, Line a – Items Unallowable Unless otherwise Provided, item (10) -Consultant fees in excess of \$500/day applies to expert panel members. Under what circumstances would AHRQ consider increasing the allowable amount for nationally recognized panel members?

Answer: This list refers to items that are unallowable unless approved by the Contracting Officer. Therefore, for any consultant fees \$500 or lower, the Contractor does not need advance approval. For fees in excess of \$500, the Contractor should submit a written request to the Contracting Officer which justifies the fee being requested.

55. Question: What level of involvement does AHRQ anticipate for both the reporter of a near miss event and the professional staff of the contractor in developing the detailed case studies selected for root cause analysis and detailed write-up for the M&M Web site?

Answer: The Contractor's professional staff may work with the reporter to solicit additional necessary detail, clarification, etc. However, as noted in Task 1.2, the reporter shall be expected to provide a detailed case report that "...includes a formal root cause analysis as well as remedial strategies..."

56. Question: Does AHRQ expect that the root cause analysis and detailed write-up will be the responsibility of the near miss event reporter, the contractor's staff, or a collaboration of both:

Answer: See the response to Question 55.

57. Question: Will AHRQ consider granting an extension of approximately one month for the proposal due date. Will AHRQ grant such an extension?

Answer: The due date for the receipt of proposals has been extended until Tuesday, April 17, 2001, at 1:00 p.m., local time.

58. Question: Can AHRQ provide a list of organizations that have expressed interest in this solicitation either in requesting the RFP, submitting a letter of intent, or submitting questions on the solicitation. Such a list may be useful in identifying potential subcontractors.

Answer: No such lists exist at this time. As this is a competitive acquisition, we cannot release names of other potential offerors.

59. **Question:** Can AHRQ's responses to questions submitted by other potential bidders be provided?

Answer: All questions and answers are being provided by means of this amendment.

60. **Question:** Are bidders expected to have recruited all or most the members of the clinical editorial panel prior to submission of the proposal, or is it acceptable for the purposes of the proposal to demonstrate the bidder's ability to recruit these individuals if they should be awarded the contract?

Answer: As noted on page 14 of the RFP, the Editorial Panel shall be finalized 2 weeks from the EDOC. Given the short period of time between the contract award date and the date the panel must be finalized, it would be judicious to have the majority of editorial panel members recruited and named keeping in mind that the Agency reserves the right of final approval. An appendix including a letter of commitment from each recruited individual would be a useful adjunct to the Offeror's proposal.

61. **Question:** What is AHRQ's target date for contract award?

Answer: Approximately June 15, 2001

62. **Question:** Can you elaborate on AHRQ's rationale for restricting the system to near miss events and excluding actual adverse events? We believe this diminishes the potential usefulness of the database.

Answer: For two reasons, the Agency has developed this project to include only near misses. First, the ratio of near misses to major injuries can run as high as 300 to 1. Thus, focusing on near misses expands the pool of events eligible for reporting to this project thereby increasing the opportunity for learning. Second, the legal climate and liability issues surrounding the reporting of and learning from errors has not yet fully matured. By limiting the project to near misses, the Agency expects to encourage reporting and reduce reporters' concerns regarding liability.

63. **Question:** Related to the above question, the RFP states that the M&M system will not include information on actual adverse events, or criminal or illegal activity. If the Contractor passively becomes aware of actual adverse events or instances of criminal or illegal activity in the performance of its duties on this contract, how would AHRQ expect the Contractor to respond to such situations? For example, if the Contractor were to receive a submission of an actual adverse event that falls within the scope of one or more existing mandatory or voluntary adverse event reporting systems, should the Contractor forward information to the relevant systems? If the Contractor receives a report of criminal or illegal activity (e.g., intentional sabotage of a drug or device intended for use in patient care), would AHRQ expect the Contractor to: a) do nothing, b) notify appropriate authorities or interested parties, c) encourage the reporter to notify appropriate authorities or interested parties, or d) take some other action?

Answer: The Contractor should reject the material from the project, return the material to the reporter who submitted it, and suggest that the reporter forward the information to the appropriate party. No material, information, documents, records, logs, etc., shall be kept for these cases.

64. Question: Does AHRQ anticipate that the server(s) housing the M&M Web site and data files will be required to reside on-site at AHRQ's offices? If so, please describe the anticipated working relationship between the Contractor's personnel to be located on-site at AHRQ, AHRQ's in-house staff, and AHRQ's IT contractor staff. For example, will the Contractor's personnel be assured of adequate workspace in AHRQ's offices? How many personnel will the Contractor be allowed to locate at AHRQ? Should bidders allocate funds in their budget for space and/or other similar physical resources to be provided by AHRQ related to the location of Contractor personnel on-site in AHRQ's offices?

Answer: The AHRQ servers housing the M&M production web site will reside at AHRQ. The Contractor should develop and test the web site in their own spaces. The Contractor shall deliver to AHRQ the final software, database and system for production operations at AHRQ. AHRQ will provide the Contractor with adequate workspace at AHRQ to install and maintain the site. AHRQ anticipates that at most one part- or full-time onsite person, if any, will be required on an ongoing basis to support operation of the site. The Contractor may be able to perform most operations and maintenance procedures remotely. AHRQ will provide the Contractor with a secure remote access authentication computer connection for any needed Contractor offsite access to facilitate their system maintenance, troubleshooting, and operations processes, as appropriate. When the Contractor is ready to begin system installation, planning and production operations, the Contractor shall coordinate with the AHRQ CIO to obtain secured access and needed space for equipment and personnel within the AHRQ computer facilities. The Contractor shall not allocate funds in their budget for AHRQ space, heat, power, air conditioning, and other environmental physical resources or Internet connectivity or firewall security services to support operating the system and locating any full- or part-time Contractor personnel onsite at AHRQ, as reasonably needed, to install and operate the system.

65. Question: Can you elaborate on AHRQ's rationale for selecting only five case abstracts per month (one in each clinical specialty) for detailed evaluation and write-up? Would AHRQ be interested in having more case studies published, if feasible and cost-effective?

Answer: The project is to be designed and bid based on the Requirements stated in the RFP. However, the Offeror may elect to submit another (i.e., alternative) proposal. If the Offeror elects to take this extra step, it must submit a second set of technical and cost proposals and clearly label them "Alternative."

66. Question: A key feature of hospital-based M&M conferences is the use of visual aids, including imaging studies, anatomical diagrams, lab test results, and other similar items. Would AHRQ want the contractor to solicit and/or accept copies of actual patient medical record and/or other information pertinent to the case, even if such information contained no data that could be used to identify an individual patient?

Answer: The Contractor shall not solicit or nor shall they accept copies of actual patient medical records.

67. Question: Can AHRQ reclassify this acquisition, for the purposes of the Small Business Program Representations (see RFP Section K, page 38, clause K.8), under NAICS code 54151, Custom Computer Programming Services? (This code is defined as follows: 54151 Computer Systems Design and Related Services: This industry comprises establishments primarily engaged in providing expertise in the field of information technologies through one or more of the following activities: (1) writing, modifying, testing, and supporting software to meet the needs of a particular customer; (2) planning and designing computer systems that integrate computer hardware, software, and communication technologies; (3) on-site management and operation of clients' computer systems and/or data processing facilities; and (4) other professional and technical computer-related advice and services. In contrast, the currently designated code 54161, Management Consulting Services, is defined as follows: "This industry comprises establishments primarily engaged in providing advice and assistance to businesses and other organizations on management issues, such as strategic and organizational planning; financial planning and budgeting; marketing objectives and policies; human resource policies, practices, and planning; production scheduling; and control planning." We believe the work to be performed under this contract, including the development of the web site, the user interface, the Oracle database that will house the Web site content, the content management back-end system, and the integration with commercially available software for Web trending and text-based database searching, is much better characterized by the 54151 series of NAICS codes. Please note that the 54151 series of codes carry small business size standards of \$18 million.)

Answer: After further review and discussion, it is determined that the NAICS Code should remain at 54161.

68. Question: The RFP distinguishes between abstracts and case summaries as follows: abstracts are reports of near misses submitted to the Contractor by healthcare professionals. Case summaries are developed from a subset of the abstracts that are chosen for more detailed analysis and publication to the Web site. Does AHRQ intend that *only* the detailed case summaries be published at the Web site, or are both the case summaries *and* the abstracts to be made publicly available at the site? If only detailed case summaries are to be made publicly available, for what purposes does AHRQ envision using the abstracts?

Answer: The website will be used to provide detailed case summary information and shall not include postings of abstracts. The case abstracts are less lengthy documents that must provide sufficient information to build a pool from which case summaries will be selected by the Editorial Panel. Additionally and as required by the RFP (see page 9, task 1.1), the case abstracts shall also be analyzed and used as input to the annual report.

69. Question: Is there a minimum percent time for the Medical Director?

Answer: The amount of time allotted to the Medical Director shall be determined by the Offeror keeping in mind that this is a substantive rather than titular key personnel.

70. **Question:** It appears that the small business plan is discussed in two different places (p. 68 and p. 71). Does this mean there are TWO small business plans that are required?

Answer: These are two separate plans. One is a Small Disadvantaged Business Participation Plan which must be completed by all offerors regardless of size. The other is the Small Business Subcontracting Plan which must be completed by all offerors except for small businesses. Please review the FAR cites if you are unfamiliar with these plans.

71. **Question:** Small Business Subcontracting Plan goals: In Section L.12.B, it states that all offerors should submit a subcontracting plan in accordance with FAR 52.219-9. This states that the base is all available subcontracting dollars. In Part G of this section, as in other sections of the solicitation, it states that the recommended percentage goals are based on the total contract value. If a plan is submitted that either meets or exceeds the AHRQ percentage goals but the basis is “available subcontracting dollars”, as per the FAR citation, would the offeror be responsive? Please clarify.

Answer: This is a discrepancy in the RFP. The FAR citation takes precedence. However, the percentage of subcontracting opportunities to the total contract value will be reviewed when negotiating the subcontracting plan.

72. **Question:** To what extent do we need to have (a) the small business relationships, (b) the editorial board, and (c) the participating hospitals on board at the outset, as opposed to developing them during the first few months of the contract?

Answer: We would like to see proposed relationships and letters of intent where possible. However, we understand that not all relationships can be established prior to contract award.

73. **Question:** Under Item C Specific Requirements, Part 1.2, refers to the design and implementation of an incentive and reward system. One of the possible rewards to those whose cases are selected for posting on the Web site is a monetary reward. Is it expected that a monetary reward will be provided to the physicians that provide near miss cases? What type of amount if any is considered acceptable?

Answer: See the response to Question 21.

74. **Question:** How should these costs be classified under the breakdown of costs of the proposal, especially since this will be an on-going cost?

Answer: These costs should be listed as direct costs in the cost proposal as necessary for each year of the contract.

75. **Question:** Part 1.3 refers to recruiting and finalizing an editorial panel. Since the panel will consist of Chief Residents representing the five medical disciplines and their time is pretty limited, an incentive program needs to also be developed for them. Monetary compensation is one of the incentives. Is it expected that a monetary reward will be provided to the panel of experts? What type of amount if any is considered acceptable?

Answer: See response to Question 21.

76. Duplicate with Question 74 - Question: How should these costs be classified under the breakdown of costs of the proposal, especially since this will also be an ongoing cost?

Answer: See response to Question 74.

77. Question: Part 2 refers to the full implementation of the web site, which also includes ongoing maintenance beyond the development period. How should these ongoing costs be classified in the proposal?

Answer: See the response to Question 74.

78. Question: Section F - Period of Performance and Delivery Schedule, Under F.3 Delivery Schedule, a delivery schedule is noted. As an example, under task 1.3 the delivery time for finalizing the editorial panel is scheduled as two weeks. How rigid is that schedule? It is our experience that it takes time to obtain the commitment of highly credential physicians because of their busy schedules.

Answer: See response to Question 60.

79. Question: Section B, Supplies or Services and Prices/Costs, B.2., items a and b refer to estimated and fixed fees. Please identify the difference between the two fees.

Answer: Section B refers to estimated costs and fixed fee; no reference is made to an estimated fee.

SECTION C**DESCRIPTION/SPECIFICATION/WORK STATEMENT****National Electronic Web-based (NEW) M & M**

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work as described in the following sections.

A. Background Information

A recent Institute of Medicine report (*To Err is Human, Building a Safer Health System*), noted medical errors as a significant source of excess morbidity, mortality, and costs. The report estimates that between 44,000 and 98,000 people die annually as a result of medical error. Costs associated with medical error are estimated to be between \$17 billion and \$29 billion annually with one half of these costs attributable to health care (Kohn).

As part of its reauthorization, the Agency for Healthcare Research and Quality is required to reduce errors in medicine by (1) identifying the causes of preventable health care errors and patient injury in health care delivery; (2) developing, demonstrating, and evaluating strategies for reducing errors and improving patient safety; and (3) disseminating such effective strategies throughout the health care industry. In carrying out these responsibilities, the Agency has developed a coordinated plan for achieving these three goals that includes projects funded through both grant and contract mechanisms.

Through morbidity and mortality conferences, hospitals and medical schools have a rich tradition of clinicians critically appraising their performance in an attempt to learn from their mistakes. While these discussions are considered open to each institution's medical practitioners (i.e., staff and trainees), the discussion and lessons learned are not shared outside the institutional walls because of concerns about liability and patient confidentiality. This limitation severely constrains opportunities for learning within the overall medical community and subjects patients and practitioners alike to unnecessary and repetitive risk.

Other fields such as aviation have addressed this type of issue by creating an open forum for discussion and learning through a de-identified process. The NASA's Aviation

Safety Reporting System (ASRS) and newsletter, *Callback*, are two notable examples. The ASRS provides for the receipt, analysis, and de-identification of aviation safety reports using a data collection form with a tear-off portion that contains the reporter's identifying information. It is collected initially so that a reporter can be contacted for clarification or further detail. Once the report is complete, the identification strip is returned to the reporter and the ASRS retains no identifying material in its files. ASRS data are used to produce periodic reports of findings that are subsequently published and distributed to the public, the aviation community, and the Federal Aviation Administration (FAA). The ASRS includes actual and potential deficiencies involving safety but does not include information concerning criminal activity. The ASRS system also includes an immunity policy which prohibits the use of any reports under the ASRS in any disciplinary action (<http://asrs.arc.nasa.gov/immunity.htm>). The *Callback* publication includes a description of several problems, their likely cause, and their potential solutions. The descriptions do not include information on the author, date of the event, etc. that could in any way identify the reporter, but do provide sufficient detail to identify and understand the problem as well as prevent their recurrence.

Health care is in need of such a mechanism to promote widespread practitioner learning and to minimize patient exposure to risk. Some health care systems have developed programs to share experiences with errors that result in adverse events as well as those that are "near misses," e.g., the Veterans Health Administration. Some systems exist to share information regarding pharmaceutical use. However, there is no broad-based, general system by which clinicians may share their experiences with "near misses."

This project expands upon the Agency's activities to reduce error and improve the delivery of safe health care. It complements a series of solicitations that form an integrated set of activities to design and test best practices for reducing errors in multiple settings of care, develop the science base to inform these efforts, improve provider education to reduce errors, capitalize on the advances in information technology to translate proven effective strategies into widespread practice, and build the capacity to further reduce errors. In particular, this procurement complements the Patient Safety Research Dissemination and Education activities planned to fund researchers and organizations (e.g. professional associations, hospital groups, national organizations) to develop, demonstrate, and evaluate new approaches to improving provider education in order to reduce errors, such as using new knowledge on patient safety and to develop curricula, continuing education, simulation models, and other provider training strategies.

This project is an initial, focused effort that builds upon traditional, physician-operated morbidity and mortality conferences. The project's end products are intended to be used by physician trainees as well as practicing physicians. Based on the success of this project, the Agency may consider broadening its efforts to include similar activities for other disciplines (e.g., nursing).

B. Objectives

The contract objectives are to: (1) Develop, test, implement, and assess a national, web-based, blame-free learning program for providers of health care that relies on reports of

“near misses”¹ and is modeled after and functions like hospital morbidity and mortality conferences; (2) advance learning from “near misses,” and (3) improve patient safety by reducing the risk for “near misses.”

C. Specific Requirements

Specifically, the contractor shall:

8. Design and develop a national, web-based, blame-free education and learning program based on “near misses” and modeled after hospital-based morbidity and mortality conferences.²

The Contractor shall design a system that regularly solicits, selects, and posts to the Web, de-identified and non-confidential medical, surgical, gynecological/obstetrical, psychiatric, and pediatric “near miss” case reports to be used for electronic discussion and learning. Electronic discussions shall promote the inclusion of comments, reviews, and dialogue from multiple disciplines including medicine, law, ethics, etc. The initial design shall include a process that promotes the periodic (e.g. monthly) receipt of brief medical, surgical, psychiatric, obstetrical/gynecological, and pediatric abstracts that can be screened for level of interest by a standing editorial panel selected by the Contractor. On a monthly basis, one selected abstract in each of the five categories shall be identified and a detailed case report for each of the five shall be developed that includes a formal root cause analysis as well as remedial strategies which can be posted on a web site for comment. One case summary per category per month will be required to be posted electronically and be open to an objective, electronic dialogue that shall be captured and analyzed.

- 1.1 Design and develop a web-based system for blame free learning and education based on “near misses” modeled on hospital based morbidity and mortality conferences. The Contractor shall (a) develop methods to solicit, screen, and select case abstracts (one for each of the five categories per month) and full case summaries (including root cause analysis and actions to prevent or remedy the “near miss”) using a standardized reporting form to facilitate data collection and analysis that results in a fully functioning electronic Morbidity and Mortality conference; (b) develop an automated system that uses off-the-shelf software to analyze pooled data and text from abstracts, full case summaries, and Web-based electronic dialogue about posted summaries, all of which shall be used as input for an annual report; and (c) develop a web-based platform with a separate domain name (e.g., National M & M) to support the program. **In designing,**

¹Near misses are defined as errors that do not result in harm or injury. The term “near miss” is synonymous with the term “close call.”

²Cases including actual harm/injury to the patient are excluded from this project.

developing, implementing, and updating this system, the Contractor shall also provide up-to date documentation (including project plan; IT architecture, database, software design; user and system requirements; software development plan; configuration management plan; QA / Testing Plan; systems design specifications; data modeling / functional modeling plan; security plan; operations and maintenance plan; disaster /backup/ recovery plan; IT benefits and performance metrics tracking plan; User Training Plan; System Deployment and Maintenance Plan)/ User / usability test certification results).

Information Technology and Web site Requirements

- Development and maintenance: The Contractor shall develop, test, document, and maintain all software, databases, and files required under this contract using industry standards and methods. The Contractor shall follow Carnegie Mellon Software Engineering Institute (SEI), Capability Maturity Model (CMM) level 2 or greater software life-cycle development process guidelines and Clinger - Cohen Act (CCA) of 1996 (Public Law 104-106) IT investment management regulations and guidelines. The Contractor shall use configuration management, requirements management, quality assurance and testing software and procedures to control, document, and time-stamp all software configuration changes, to perform software check-in/out, version, build and software release control, to document, track and trace requirements to design and test cases, and to perform system testing and other industry standard software life cycle management procedures. The Contractor shall use a software configuration management commercial off-the-shelf system approved by the Project Officer.

- Security and confidentiality: The Contractor shall protect the security and confidentiality of the databases and system files.

- Privacy: The web site shall be maintained as a public service. However, the Contractor may collect the name of the domain users use to access the site, the type of browser and operating system the user used to access the site, the date and time of the users visit, the pages visited, and the address of the web site the user came from when referred by another site. Keywords entered into the search engine of the web site may also be tracked. The Contractor shall not require the provision of personal information to visit the web site. Individual, personal information shall not be automatically collected but may be collected to respond to a user's message or to fulfill the stated purpose of any communication initiated by a user. All communication to the web site, including customer feedback, shall be destroyed at the end of the project.

- Disaster recovery: The Contractor shall develop and implement an effective information technology disaster recovery plan.
- Documentation: The Contractor shall provide documentation of all proposed hardware, software, security, backup/recovery, and other information technology infrastructure and components and solutions needed to support this project. **The Contractor shall prepare and maintain current electronic project IT documentation as described in Section 5.4 below. A copy of all current project IT documents shall be made accessible at all times for secured remote online access by the government Project Officer and designated officials.**
- Information technology solutions: The Contractor shall obtain Project Officer approval for all proposed information technology solutions.
- Database management and model requirements: The Contractor shall use the **latest enterprise version of the** Oracle Database System for all database management needs of the project and shall use **the latest version of Oracle Designer** to document all data and functional model requirements of the system.
- Hardware and software procurement: The Government reserves the option to procure and deliver as Government Furnished Equipment (GFE) all information technology hardware and software required to operating and maintaining system(s) used in this project.
- Information collection: In collecting information, the Contractor shall collect only those data necessary for the performance of the project. In collecting data and using electronic mail, Internet Protocol addresses, user statistics, activity logs, and similar data (e.g., cookie technology) the Contractor must make public notice thereof on the website and elsewhere as necessary. **The Contractor will not use any cookie technology without written prior approval from the Project Officer.**
- Access standards: The Contractor shall ensure that the web site is "Bobby Approved" and meets the Workforce Investment Act of 1998 and Section 508 of the Rehabilitation Act of 1973 regulations for website design and operations. In particular, the Contractor shall take all appropriate steps to ensure that the electronic and information technologies used in the system are accessible to individuals with disabilities to the same extent as those without disabilities. For example, frames may be used as long as an option to turn off the frames is supported. If the Contractor proposes using frames and graphics, the Contractor must provide alternative, equal access to all content (i.e., ASCII text files only option) to be in compliance with the Americans with Disabilities Act (ADA). A text equivalent for every non-text element shall be provided. Pages that use table formatting must also be available in formats (i.e., plain text) for browsers that cannot render tables. Web

pages shall be designed so that all information required for navigation or meaning is not dependent on the ability to identify specific colors. Changes in the natural language of a document's text and any text equivalents shall be clearly identified. Documents shall be organized so they are readable without requiring an associated style sheet. Web pages shall update equivalents for dynamic content whenever the dynamic content changes. Redundant text links shall be provided for each active region of a server-side image map. Client-side image maps shall be used whenever possible in place of service-side image maps. Data tables shall provide identification of row and column headers. Markup shall be used to associate data cells and header cells for data tables that have two or more logical levels of row or column headers. Frames shall be titled with text that facilitates frame identification and navigation. Pages shall be usable when scripts, applets, or other programmatic objects are turned off or are not supported, or shall provide equivalent information on an alternative accessible page. Equivalent alternatives for any multimedia presentation shall be synchronized with the presentation. An appropriate method shall be used to facilitate the easy tracking of page content that provides users of assistive technology the option to skip repetitive navigation links (<http://www.section508.gov/docs/accessstandards.htm>).

- 1.2 Design and implement an incentive and reward system. The Contractor shall develop and implement a system that provides effective incentives to those targeted to submit abstracts and rewards those who are selected to submit full case summaries that will be posted on the project's Web site. This incentive and reward system must be robust enough to maintain the confidentiality of reporters, facilities, cases, etc. yet flexible enough to allow dispersal of the incentives and rewards to those whose cases are selected for posting on the Web site.
- 1.3 Recruit and finalize an editorial panel not to exceed 15 members. The Contractor shall recruit and finalize an editorial panel that will review abstracts, select cases suitable for full case summaries, and review and comment on the workplan and annual reports. Candidates shall be selected based on their national recognition and relevant background and responsibilities to include, for example, medical education, clinical practice specialty, improving patient safety and quality, health care systems, law, ethics, administration, informatics, human factors engineering, etc. In addition, the editorial panel shall include five Chief Residents representing medicine, surgery, obstetrics/gynecology, psychiatry, and pediatrics. All panel members are subject to final approval by the Project Officer.
- 1.4 Develop a confidential, legally protected system. The Contractor shall develop a method to ensure complete confidentiality and legal protection for all abstracts, case summaries, and their reporters, facilities, patients, etc. but which also enables follow-back to clarify abstracts and case summaries as well as provide the necessary rewards for reporters whose

case summaries are selected for posting on the web.

2. User-test and modify the national, web-based, blame-free learning program. The Contractor shall test the program with a small sample of individuals representative of the types of professionals (e.g., residents and practicing physicians) expected to use the web site in each of five categories (i.e., medical, surgical, obstetric/ gynecological, psychiatric, pediatric). Feedback shall be solicited and analyzed, and the program shall be modified as necessary and appropriate.
3. Fully implement the national, web-based, blame-free education and learning program. The Contractor shall (a) implement the web-based program; (b) solicit cases (both abstracts and full case summaries) in each of the five categories as selected from target audiences; (c) post case summaries; (d) monitor and capture electronic dialogue regarding the posted summaries; and (e) analyze data from all formats (abstracts, summaries, and electronic dialogue) to report on “near misses” and methods to prevent or reduce their occurrence.
4. Assess the utility and effectiveness of the national, web-based, blame-free education and learning program. The Contractor shall develop and implement a method to evaluate the usefulness and effectiveness of this program with various targeted audiences on a periodic, on-going basis. Periodically the program shall be modified as necessary to ensure its effectiveness and usefulness for national education and learning from the medical, surgical, obstetric/gynecological, psychiatric, and pediatric “near misses” included in the project.
5. Project management
 - 5.1 The Contractor shall meet with the Project Officer and other essential staff, as designated by the Agency, within one week of contract award to review the scope of work and delivery schedule, delineate roles and responsibilities, and establish communication protocols.
 - 5.2 The Contractor shall develop and submit a draft workplan for Agency approval that is based on the proposal submitted and discussions in task 5.1. In addition to the substantive and management content of the workplan (both draft and final versions), it shall also include the IT project plan; IT architecture, database, software design; user and system requirements; software development plan; configuration management plan; QA / Testing Plan; systems design specifications; data modeling / functional modeling plan; security plan; operations and maintenance plan; disaster /backup/ recovery plan; IT benefits and performance metrics tracking plan; User Training Plan; System Deployment and Maintenance Plan).
 - 5.3 The Contractor shall develop and submit a final workplan for Agency

approval based on Agency responses to task 5.2.

- 5.4 The Contractor shall prepare a monthly progress report that includes:
- A short description of the project objectives.
 - A brief narrative on what was accomplished during the reporting period for each requirement including a summation of the cost and level of effort expended for each task.
 - Preliminary or interim results, conclusions, trends, or problems that the Contractor identifies as of importance to the Government.
 - Problems or delays that the Contractor has experienced in the conduct of performance requirements including what specific action is proposed to alleviate the problem(s).

A separate section describing all information technology related work accomplished during the month including expected completion dates, outstanding issues, problems, recommended solutions to complete the work, expenses invoiced to-date, and costs anticipated for the following month. Also, the section will include electronic attachments containing the following updated documents: a project plan with work breakdown and task assignments, planned vs. actual cost and schedule reporting, risk management planning and tracking; subcontractor project task tracking and status reporting; a software development plan; requirements specifications and traceability to design and testing scripts; system design architectures, web site designs, database design, data and work flows; software coding and inline documentation; quality assurance plan; software test plans and test results reports; configuration management plan; user feedback, problems and issues reports; software change and bug reports; user / usability test plan and test results; training and deployment plans, procedures and results; operations / maintenance plans, procedures and status reports; site usage tracking reports including usage patterns, any suspect usage events, patterns and anomalies; system and user performance metrics and measurements; system user benefits and outcomes tracking; and other appropriate documents to adhere to industry standard SEI CMM level 2 processes and Clinger-Cohen Act IT project management regulations and guidelines. A separate section including website usage shall also be required and the Contractor shall use Web-Trends software for preparing this information.

- 5.5 Prepare draft and final annual reports. The content and format of these reports shall be determined in consultation with the Project Officer.

All systems documentation prepared and delivered in the support of this contract shall be maintained in an electronic document management and filing system, shall be maintained current throughout the contract life-cycle, and shall be

accessible to the government for review at any time during the life of the contract.

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AMENDMENT 0001

SECTION F - PERIOD OF PERFORMANCE AND DELIVERY SCHEDULE

F.1 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates the following clause by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be assessed electronically at this address: <http://www.gov.far>.

<u>FAR Clause No.</u>	<u>Title and Date</u>
52.242-15	Stop Work Order (AUG 1989) Alternate I (APRIL 1984)

F.2 PERIOD OF PERFORMANCE

The period of performance for the Base Period of the contract shall be from the effective date of the contract through 24 months thereafter. The period of performance for the Option Period, if exercised, shall be for 12 months following the completion of the Base Period.

F.3 DELIVERY SCHEDULE

The items specified for delivery below are subject to the review and approval of the Project Officer before final acceptance. The Contractor shall be required to make revisions deemed necessary by the Project Officer.

The Contractor shall produce the following scheduled reports/deliverables in the amount, and within the time frame indicated. Deliverables shall be submitted to the Project Officer, Agency for Healthcare Research and Quality, 2101 East Jefferson St., Rockville, Maryland 20852 (Phone: 301-594-1824).

The Contractor shall submit the following items in accordance with the stated delivery schedule as noted below:

Item	Task	Description	Quantity	Delivery
1	5.1	Meet with Project Officer and other Agency staff	--	1 week from the effective date of the contract (EDOC)
2	1.3	Finalize editorial panel	--	2 weeks from EDOC
3	5.2	<u>Draft work plan</u>	5 (4 hardcopy and 1 electronic)	3 weeks from EDOC
4 *	5.3	<u>Final work plan</u>	5 (4 hardcopy and 1 electronic)	6 weeks from EDOC
5	1.1	<u>Design and user-test system</u>	--	6 months from EDOC
6	2	<u>Modify system</u>	--	11 months from EDOC
7	3	<u>Implement system:</u>	--	12 months from EDOC
8	3	Hold Editorial Panel meetings		As necessary for posting monthly cases for each specialty
9	3	Post case abstracts to the web	5 cases per month, i.e., 1 per specialty area	12 months from EDOC and monthly thereafter
10	4	Assess system	--	18 months from EDOC and on-going thereafter
11	5.5	Draft annual report	5 (4 hardcopy and 1 electronic)	12 and 23 months from EDOC

Item	Task	Description	Quantity	Delivery
12 *	5.5	Final annual report	5 (4 hardcopy and 1 electronic)	13 and 24 months from EDOC
13 *	5.4	Monthly progress report	5 (4 hardcopy and 1 electronic)	10 days after the end of each reporting month

Deliverables for Option Year 1				
Item	Task	Description	Quantity	Delivery
14	3	Post case abstracts to the web	5 cases per month, i.e., 1 per month per specialty area	25 th month from EDOC and monthly thereafter
15	3	Hold Editorial Panel meetings	--	As necessary
16	4	Assess system	--	On-going
17	5.5	Draft annual report	5 (4 hardcopy and 1 electronic)	35 months from EDOC
18 *	5.5	Final annual report	5 (4 hardcopy and 1 electronic)	36 months from EDOC
19 *	5.4	Monthly progress report	5 (4 hardcopy and 1 electronic)	10 days after the end of each reporting month

*In addition, one copy of the final work plan, the monthly progress reports and annual final reports shall be submitted to the Contracting Officer at the following address:

Agency for Healthcare Research and Quality
ATTN: Contracting Officer
Division of Contracts Management
2101 East Jefferson Street, Suite 601
Rockville, Maryland 20852

In addition, the following reports are required to be submitted to the Contracting Officer for the base period and the option period, if exercised:

Type of Report	Date Due	Quantity
Subcontracting Report for Individual Contracts (SF-294)	April 30 (annually) October 30 (annually)	3 each (1 original and 2 copies)
Summary Subcontractor Report (SF-295)	October 30 (annually)	1 copy to the Office of Small and Disadvantaged Business Utilization (DHHS)
Small Disadvantaged Business Participation Report (OF-312)	At contract completion	3 each (1 original and 2 copies)